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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,460	09/11/2003	Robert Boock	022956-0223	7148
21125 7590 05/23/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER HOEKSTRA, JEFFREY GERDEN	
			ART UNIT 3736	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/661,460

Applicant(s)

BOOCK ET AL.

Examiner

JEFFREY G. HOEKSTRA

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-25, 31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-25, 31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Notice of Reply

1. In response to the Reply filed on 02/06/2008, the following is/are set forth:

Election/Restrictions

2. Applicant's election with traverse of Set 1 Species D, embodiment drawn to the tissue harvesting tip shown in Figure 3D, Set 2 Species EE, embodiment drawn to the cutting member shown in Figure 4E, and Set 3 Species CCC, embodiment drawn to "translating and rotating", in the reply filed on 02/06/2008 is acknowledged.
3. With respect Applicant's traversal of the Requirement for Election in Sets 1 and 2, the traversal is on the ground(s) that no serious burden exists and all the embodiments have been searched and/or examined. This is not found persuasive because as claimed and disclosed the Species in Sets 1 and 2 are mutually exclusive, patentably distinct species that are not obvious variants of each other based on the record. Moreover, as claimed the species are independent or distinct because they are substantially dissimilar and structurally divergent means for configuring a tissue harvesting tip and cutting member to cut and harvest tissue in a tissue sampling device. The Examiner notes and agrees with Applicant's indication that with respect to Species D claims 1-11, 14-16, 18-25, and 31 are generic. The Examiner notes and agrees with Applicant's indication that with respect to Species EE all claims are generic.
4. With respect to Applicant's traversal of the Requirement for Election in Set 3, the traversal is on the ground(s) that as disclosed and claimed all embodiments both rotate

and translate. This is found persuasive and the requirement for Election of Species in Set 3 is withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

5. Claim 12 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/06/2008.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

7. Claim 1 is objected to because of the following informalities: the positive recitation of "and" in line 9 should apparently be deleted. Appropriate correction is required.

8. Claims 6 and 7 are objected to because of the following informalities: the positive recitations of "the angle" in line 1 appear to lack antecedent basis and may render the claims indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4, 11, 13-16, 18, 21-25, and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wulfman et al. (US 2002/0007190 A1, hereinafter Wulfman).

11. For claim 1, Wulfman discloses a tissue extraction and maceration device (Abstract), comprising:

- an outer tube (40) having a substantially open distal end (as best seen in Figures 5, 6, and 13A-13C) that is adapted to be placed on a tissue surface (as best seen in Figure 13A) (paragraphs 88-89);
- a shaft (25) rotatably disposed within the outer tube (as best seen in Figure 13C) (paragraphs 74-76) and movable between a first, proximal position in which the shaft is fully disposed within the outer tube (as best seen in Figure 13A), and a second, distal position in which a portion of a distal end of the shaft extends through the substantially open distal end of the outer tube (as best seen in Figure 13C);
- a tissue harvesting tip (90) formed on the distal end of the shaft (as best seen in Figures 8A and 8B), the tissue harvesting tip being effective to excise a tissue sample (paragraph 95-97);
- a cutting member (100) coupled to the shaft at a position proximal to the tissue harvesting tip (as best seen in Figures 8A and 8B), the cutting member being

effective to macerate a tissue sample excised by the tissue harvesting tip (paragraphs 95-97); and

- a sizing screen (169) (paragraphs 109-110) disposed within the outer tube and positioned proximal to the tissue harvesting tip and the cutting member (as best seen in Figure 12).
12. For claim 2, Wulfman discloses the tissue extraction and maceration device, further comprising: a biasing element (20) (paragraphs 72-73) effective to bias the shaft to the proximal position (as best seen in Figures 1 and 13A-13C).
13. For claim 3, Wulfman discloses the tissue extraction and maceration device, further comprising: a trigger mechanism (12) connected to the shaft, wherein, upon actuation, the trigger mechanism is effective to overcome the biasing force to move the shaft from the proximal position to the distal position (paragraph 72).
14. For claim 4, Wulfman discloses the tissue extraction and maceration device, wherein the open distal end of the outer tube is adapted to form a seal with a tissue surface (paragraphs 88-89).
15. For claim 10, Wulfman discloses the tissue extraction and maceration device, wherein the cutting member comprises at least one blade member (102) extending radially from the shaft (paragraph 97) (as best seen in Figures 8A and 8B).
16. For claim 11, Wulfman discloses the tissue extraction and maceration device, wherein each blade member has a curved shape (paragraph 97) (as best seen in Figures 8A and 8B).

17. For claim 13, Wulfman discloses the tissue extraction and maceration device, wherein the harvesting tip comprises a substantially semi-cylindrical housing (90) having a cutting surface (94) formed around a periphery thereof (paragraph 95-96) (as best seen in Figures 8A and 8B).

18. For claims 14-16, Wulfman discloses the tissue extraction and maceration device, wherein the harvesting tip is adapted to penetrate tissue to remove a predetermined volume of tissue when moved from the proximal position to the distal position (paragraph 18) and when the harvesting tip is moved from the proximal position to the distal position the predetermined volume of tissue per tissue sample collected is capable of being about 0.9 cm^3 .

19. For claim 18, Wulfman discloses the tissue extraction and maceration device, wherein the sizing screen includes openings (171) formed therein (as best seen in Figure 12), wherein the openings are defined by a wall (169) having an upstream edge (as best seen in Figure 12) that is capable of cutting tissue having a size greater than the circumference of the openings (paragraphs 109-112).

20. For claim 21, Wulfman discloses the tissue extraction and maceration device further comprising a driver mechanism (24) (paragraph 74-76) coupled to the shaft (as best seen in Figure 1) and effective to rotate the shaft at a speed in the range of about 100 to 5000 rpm (paragraph 75).

21. For claim 22, Wulfman discloses the tissue extraction and maceration device, wherein the harvesting tip of the shaft is adapted to extend beyond the outer tube by a predetermined distance (as best seen in Figure 13C).

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22. For claim 23, Wulfman discloses the tissue extraction and maceration device, wherein the predetermined distance is capable of being in the range of about 1 mm to 5 mm (as best seen in Figure 13C).

23. For claim 24, Wulfman discloses the tissue extraction and maceration device, wherein the predetermined distance is capable of being about 3 mm (as best seen in Figure 13C).

24. For claim 25, Wulfman discloses the tissue extraction and maceration device, wherein the outer tube is coupled to a vacuum pump (18) that is effective to draw tissue through at least a portion of the outer tube (paragraphs 73 and 83).

25. For claim 31, Wulfman discloses a tissue harvesting device (Abstract), comprising:

- a handle housing (12) having a trigger coupled thereto (paragraphs 67, 71, and 72);
- an outer tube (120) extending from the handle housing and rotatable relative to the handle housing (paragraph 100) (as best seen in Figure 9A);
- a shaft (25) rotatably disposed within the outer tube and movable between a first, proximal position in which the shaft is fully disposed within the outer tube (as best seen in Figure 13A), and a second, distal position in which a portion of a distal end of the shaft extends through a substantially open distal end of the outer tube (as best seen in Figure 13C);

- a tissue harvesting tip (113) formed on the distal end of the shaft (as best seen in Figure 9A), the tissue harvesting tip being effective to excise a tissue sample (paragraphs 95-98); and
- a cutting member (115) coupled to the shaft at a position proximal to the tissue harvesting tip (as best seen in Figure 9A), the cutting member being effective to macerate a tissue sample excised by the tissue harvesting tip (paragraphs 95- 98).

26. For claim 32, Wulfman discloses a tissue harvesting device, comprising:

- a substantially hollow cylindrical member (252') (as best seen in Figure 24) (paragraphs 140-142) having a substantially flattened distal end (as best seen in Figures 23 and 24) and a plurality of cutting teeth (254') formed around an outer sidewall thereof (as best seen in Figure 24) and having openings (482) formed therein and extending into an inner lumen (236') of the cylindrical member (paragraph 140), the plurality of cutting teeth protruding from the outer sidewall such that the plurality of cutting teeth are effective to excise a plurality of tissue samples upon axial rotation of the cylindrical member and to deliver the plurality of tissue samples to the inner lumen (paragraphs 140-142).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

29. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman in view of Wiley (US 5,489,291). Wulfman discloses the tissue extraction, maceration, and harvesting device, as set forth above, except for expressly disclosing the substantially open distal end of the outer tube is defined by an edge wall at an angle that is angled with respect to a longitudinal axis of the outer tube, wherein the angle is in the range of about 30° to 75° and about 40°, and wherein the edge wall includes surface features comprising ridges formed thereon. Wiley discloses a tissue extraction, maceration and harvesting device (26), comprising *inter alia*: an outer tube (34) (as best seen in Figure 3) having a substantially open distal end (as best seen in Figure 3) defining an edge wall (38) at an angle (as best seen in Figure 3) that is angled with respect to a longitudinal axis of the outer tube (as best seen in Figure 3), wherein the angle is in the range of about 30° to 75° and about 40° (as best seen in Figure 3), and wherein the edge wall includes surface features comprising ridges formed thereon

(column 4 line 59 - column 5 line 2). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Wulfman and Wiley. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the tissue extraction, maceration, and harvesting device as taught by Wulfman with the tissue extraction, maceration, and harvesting device as taught by Wiley to achieve the predictable results of severing tissue.

30. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman. Wulfman discloses the tissue extraction, maceration, and harvesting device, as set forth above, except for expressly disclosing the sizing screen having a diameter of about 1 mm. However, Wulfman teaches configuring the size of the aspiration ports with a "sufficient cross-section to remove desired volumes of fluids and particulates" (paragraph 104), thus teaching a tissue extraction, maceration, and harvesting device including a sizing screen having a diameter in the range of about 0.7 mm to 1.3 mm.

31. Thus, Wulfman discloses the claimed invention but does not disclose expressly the sizing screen having a diameter of about 1 mm. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the tissue extraction, maceration, and harvesting device as taught by Wulfman with the sizing

screen having a diameter of about 1 mm, because Applicant has not disclosed that sizing screen having a diameter of about 1 mm provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with aspiration ports with a "sufficient cross-section to remove desired volumes of fluids and particulates" (paragraph 104) as taught by Wulfman, because it provides appropriately sized ports or sizes screens and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Wulfman. Therefore, it would have been an obvious matter of design choice to modify Wulfman to obtain the invention as specified in the claim(s).

Response to Arguments

32. Applicant's arguments with respect to claims 1-16, 18-25, and 31-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

33. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Banko (US 3,937,222), Thimsen et al. (US 4,649,919), and Johnson et al. (US 4,842,578) are each expressly concerned with and disclose surgical instruments for cutting and removing tissue..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is

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(571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736